**FORM 19.**

*Regulation 18 (1)*

**Application for a Licence to Manufacture Drugs**

Physical address of premises \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

P. O. Box No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax \_\_\_\_\_\_\_\_\_\_\_\_\_

Name of applicant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Qualifications (pharmaceutical) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Other) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the application made for —

a partnership \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

a company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If applying on behalf of a company—

Physical address of registered office \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

P. O. Box No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Tel. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax \_\_\_\_\_\_\_\_\_\_\_\_\_

Name of managing director \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If applying on behalf of a company or partnership give the following information for all partners or directors—

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Qualifications\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has the applicant or any partner or director been convicted, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs

within or outside Uganda? Yes/No

If “yes”, give details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of business under the Act been refused or

cancelled? Yes/No

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If “yes”, give details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does the applicant or any partner or director currently hold a licence to operate any type of business under the Act, including the business of selling class C drugs, at any other premises? Yes/No

If “yes”, give details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and registration number of the pharmacist in charge of the manufacturing processes \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and registration number of pharmacist or name of the chemist to be in charge of quality control and assurance \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Names, qualifications and registration number of the other pharmacists employed and names of the other or chemists employed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I certify that the above information is correct and apply for a licence to manufacture drugs at the above-named premises.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature of applicant* *Date*

**For Authority use:**

Suitability of premises certificated checked Yes/No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(Signature)*

Applicant’s information checked and verified Yes/No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(Signature)*

Licence to manufacture drugs approved/not approved

If not approved, give reasons \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*For Authority* *Date*

**FORM 20**

*Regulations 19 (4)*

**Application for Assessment for Compliance with Good**

**Manufacturing Practice Guidelines**

*(A separate application form should be filled for each site)*

1. Particulars of applicant/licence holder

Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Telephone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Fax \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Particulars of site to be inspected

Name of manufacturing site\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical address (if different from number 1)

Country \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Tel\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Fax\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Contact person at manufacturing site

Name of contact person\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Fax:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Type of drugs manufactured (*Tick where applicable*)

(a) Human only (b) veterinary only (c) human & veterinary

1. Inspection type *(Please tick where applicable*)
	1. First inspection
	2. Routine re- inspection (previous inspection date…………………)
	3. Re-inspection after failure ……………………………………....
	4. Other (please specify)……………………………………………

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1. Lines to be inspected



*Tick where*

*Dosage form* *\*category \*\*activities applicable*

Tablets

Capsules

Injections (SVP)#

Injections (LVP) #

Oral liquids

Powders for oral suspension

Creams/Ointments/lotions

Others (specify)

\*Category means, Beta lactam (Penicillin), Beta lactam (Cephalosporins), Non-beta lactam, Biologicals, Vaccines, Hormones, Cytotoxic products.

\*\*Activity means any step in the manufacturing process that is conducted at the site such as the complete manufacture of dosage form, primary or secondary packaging, quality control and warehousing.

#

Small Volume Parenterals (SVP) refers to packs of 100ml or less and Large Volume Parenterals (LVP) are packs of more than 100ml.

1. Registration of drugs

Has the applicant applied for registration of the drugs?

No Yes

If yes, list the drugs. (*Attach a separate sheet if needed*) …………….

1. Inspection dates

In order to schedule an inspection, the applicant should indicate an approximate date from which the applicant may be ready for the inspection. If this date changes after the application is submitted, the applicant shall notify the Authority as soon as possible.

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Approximate date when the facility is to ready for inspection ……/…../……

*(For re-inspections, not more than three months after expiry of GMP validity)* The actual date of the audit will be advised to the applicant by the Authority.

Site master file

It is requested that the applicant encloses with this application form a copy of

the site master file (not more than 25 pages).

Enclosed -Yes  No 

I hereby certify that the above information is correct and apply for Good Manufacturing Practice inspection of the above-named site or sites.

Signature of applicant………………………. Date……………………………

Name of applicant……………………………………………………………..

**FORM 21**

*Regulation 19 (5)*

**Certificate of Compliance with Good Manufacturing**

**Practice Guidelines**

**The National Drug Policy and Authority Act, Cap 206**

Certificate No. ……………………

This is to certify that the drug manufacturing facility:

Name of facility \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Physical address of facility \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Licence number of the manufacturer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Has been inspected by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the inspection carried out \_\_\_\_\_\_\_\_\_\_\_\_ [dd/mm/yyyy], it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

Table 1: Approved lines



|  |  |  |  |
| --- | --- | --- | --- |
| *No.* | *Dosage form* | *Category* | *Activities* |

1.

2.

3.

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid until \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [dd/mm/yyyy]. It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

……………………………………….

*For the Authority*